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Guidance for the Reregistration of Manufacturing-Use and Certain End-Use Pesticide Products Containing Monuron-TCA (035502) as the Active Ingredient

(U.S.) Environmental Protection Agency
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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS CONTAINING MONURON-TCA (035502) AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages 69
	20. Security Class (This Page)	22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77) (Formerly NTIS-35) Department of Commerce

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Note: Appendices V-1, V-5 and V-6 are not germane to this document and are not included.

Also attached to this document are copies of the letters used to transmit the document to registrants and notify them of studies required.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(g), as amended in 1978, directs the Environmental Protection Agency (EPA) to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth certain of the requirements for registration and reregistration of all manufacturing-use products (MPs) containing the subject chemical as the sole active ingredient. These requirements include: that certain scientific data be submitted and that certain standards of toxicity, composition, labeling, and packaging be met. Registrants of MPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements for those end-use products which contain the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, and VI and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document and with the requirements contained in subsequent information from EPA about compliance with certain data support requirements.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use products' registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

This guidance document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This chapter describes the regulatory position of the Environmental Protection Agency ("the Agency") on Monuron-TCA based on an evaluation of all registered manufacturing-use products (MUP's) containing Monuron-TCA as the sole active ingredient. Future requests for registrations of substantially similar products will be covered by this standard. Dissimilar products will require amendments to the standard. This document provides the rationale for the Agency's position and the criteria for registration. It also discusses labeling requirements and tolerances.

"Monuron-TCA" is the accepted common name for the compound, 3-(p-chlorophenyl)-1,1-dimethylurea trichloroacetate recognized by the American National Standards Institute. The Trade and other name for Monuron-TCA is Urox. The Chemical Abstracts Service (CAS) Registry number is 140-41-0. The Office of Pesticide Program's internal Control Number (EPA Shaughnessy number) is 035502.

B. USE PROFILE

Monuron-TCA is a substituted urea herbicide for control of certain woody plants, certain annual and perennial grasses, broadleaf weeds, and algae, to be used on agricultural premises (around buildings, fencerows, farm roads), rights-of-way (highway, railroad, and utility rights-of-way), commercial and industrial premises (tank farms, lumber yards, storage areas, plant sites, parking lots, fencerows), domestic dwellings, schools, (fencerows, parking lots, playgrounds), and in irrigation and drainage ditches.

It was patented by Allied Chemical Corporation in 1957, (US Patent No. 2,782,112) and was first registered for use in 1958. The current domestic producer of Monuron-TCA is Hopkins Agricultural Chemical Company.

Monuron-TCA is available as a sole active ingredient in granular and dust formulations (5.5%, 11.0%, and 22.0%), and emulsified concentrate, pressurized liquid, ready-to-use solutions, and soluble concentrates (3.19%, 6.40%, 12.81%, and 32.25%).

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on Monuron-TCA, the Agency has made the following determinations:

1. Manufacturing-use pesticide products containing Monuron-TCA as a sole active ingredient may be registered for sale, distribution, formulation and use in the United States, subject to the terms and conditions specified in this standard. Applicants having products not conforming to this standard must apply to amend the document so those products containing Monuron-TCA may be registered and reregistered under this standard. Mixtures and end-use products containing Monuron-TCA are not covered under this standard.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of Monuron-TCA specified in this standard.

3. All of the toxicity data cited as supporting data for the registration of Monuron-TCA are considered to be supplementary or invalid.

4. The available Monuron-TCA environmental fate data are insufficient to fully assess the chemical at this time. When additional environmental fate data are submitted, a complete environmental exposure assessment can be made.

5. There are insufficient data to characterize the toxic effects of Monuron-TCA on aquatic organisms, fish and wildlife. When additional ecological effects data are submitted, a complete hazard assessment can be made.

6. The available Monuron-TCA product chemistry data are insufficient to fully assess the chemical at this time. The data gaps outlined in the product chemistry data tables are tests needed to adequately support the registration of a Monuron-TCA product.

7. The Agency now considers that the use of Monuron-TCA on drainage ditches in Florida citrus groves as a food use. Residue data to support this use are not available. Monuron-TCA residue data and/or other data demonstrating that such use will or will not result in residues in water or in crops receiving irrigation water will be required. If residues occur in crops, tolerances will be required.

8. Registrants must provide or agree to develop additional data, as specified in the tables attached to this standard, in order to maintain existing registrations or to permit new Monuron-TCA registrations.

9. Because there are no established tolerances for Monuron-TCA, residues in food or feed will not be permitted from uses approved in any registration under this standard.

D. REGULATORY RATIONALE

The Agency has determined the following:

1. As stated above, all of the toxicology data are considered invalid or supplementary and therefore, do not permit conclusions as to the safety of Monuron-TCA. However, the available supplementary data indicate that Monuron-TCA has a low order of toxicity (TOX CAT III) by the oral and dermal route routes of exposure, but high acute oral doses have produced symptoms of anemia, methemoglobinemia and and pathological changes in the spleen, bone marrow, liver and kidneys of test animals. The available supplementary longer term studies further demonstrated a similar potential for affecting these organs, as well as the lung and testes, at high dietary levels.

The closely related compound, monuron, has been evaluated as a potential oncogen. The National Toxicology Program (NTP), Public Health Service (PHS) tested and recently completed its evaluations in both rats and mice. These report are under peer review within NTP/PHS and were not available in time to be considered in this review.

2. The Agency believes that the use of Monuron-TCA on drainage ditches in Florida citrus groves is a food use because of the potential for residues to be found in the crop. If this use is to be approved, Monuron-TCA residue data and/or other data demonstrating that such use will or will not result in residues in water or in crops receiving irrigation water will be required. If residues occur in crops, tolerances will be required.

3. It is not the Agency's policy to cancel or to withhold registration merely because data are missing or inadequate (See Sections 3(c)(2)(B) and 3(C)(7) of the FIFRA). Rather, publication of this standard provides a mechanism for identifying data needs and registration under the standard and allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of Monuron-TCA.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be subject to this standard, products must meet the following conditions:

1. Contain Monuron-TCA as the sole active ingredient and

2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including commmiting to fill data gaps on a schedule agreed to by both this agency and the applicant, and when applicable, offering to pay compensation for data to the extent required by Section 3(c) (1) (D) of the FIFRA. Applicants for registration under this standard must follow the instructions contained in this standard and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Manufacturing use products must contain at least 32.25 percent Monuron-TCA as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use Monuron-TCA products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registerable under this standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing Monuron-TCA within acute toxicity category III provided that the labeling of those products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing Monuron-TCA may be labeled for formulation only into end-use products for use as herbicides to control certain woody plants, annual and perennial grasses, broadleaf weeds, and algae, to be used on agricultural premises (around buildings, fencerows, farm roads,), rights-of-way (highway, railroad, and utility rights-of-way), commercial and industrial premises (tank farms, lumber yards, storage areas, plant sites, parking lots, fencerows), domestic dwellings, schools, (fencerows, parking lots, playgrounds), and in irrigation and drainage ditches.

G. REQUIRED LABELING

All technical grade, manufacturing-use, and end-use products containing Monuron-TCA must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

H. TOLERANCE REASSESSMENT

There are no established tolerances for Monuron-TCA in the United States and no pending registrations or requests for establishment of tolerances or exemptions from requirements of a tolerance for Monuron-TCA.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix III-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1/] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines [2/], or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix III-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	No	-	Yes 3/
61-2 - Statement of Composition	TGAI	No	-	Yes 3/
61-3 - Discussion of Formation of Ingredients	TGAI	No	-	Yes 3/
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No	-	Yes 3/
62-2 - Certification of Limits	TGAI	No	-	Yes 3/
62-3 - Analytical Methods for Enforcement of Limits	TGAI	No	-	Yes 3/
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No	-	Yes 4/
63-3 - Physical State	TGAI	Partial	005021075	Yes 4/
63-4 - Odor	TGAI	No	-	Yes 4/
63-5 - Melting Point	TGAI	No	-	Yes 4/
63-6 - Boiling Point	TGAI	n/a	-	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	-	Yes 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Partial	005021082	Yes 4/
63- 9 - Vapor Pressure	TGAI OR PAI	No	-	Yes 4/
63-10 - Dissociation constant	TGAI OR PAI	No	-	Yes 4/
63-11 - Octanol/water partition coefficient	PAI	Partial	005018258	Yes 4/
63-12 - pH	TGAI	No	-	Yes 4/
63-13 - Stability	TGAI	No	-	Yes 4/
Other Requirements:				
64- 1 - Submittal of samples	Choice	n/a 5/		

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

§158.120 Product Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than six months from the issue date of the guidance package.
3/ Certain of the required data are available to the Agency in previously submitted Confidential Statements of Formula. The Agency, however, has noted that in most cases these data are both incomplete or are in need of updating. The Agency, therefore, will require the submission of data for each technical compound undergoing registration or reregistration.
4/ Elements of the indicated data have been located by the Agency within standard references. The Agency cannot, however, apply this information to currently produced technical products due to possible variations in synthesis processes. The indicated physical chemical properties data will, therefore, be required for each technical product undergoing registration or reregistration.
5/ N/a: Not applicable= Data requirement is not necessary for purposes of this standand.

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition [1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2/]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)	[Reserved] [3/]			
- Plants				
- Livestock				
171-4 - Residue Analytical Method	[Reserved] [3/]			
- Plant residues				
- Animal residues				
171-4 - Storage Stability Data	[Reserved] [3/]			
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use	[Reserved] [3/]			
- Crop Group #1 - (Name)				
o Crop 1 (Name)				
-- Crop field trials				
-- Processed Food/Feed				
o Crop 2, etc.				
-- Crop field trials				
-- Processed Food/Feed				
- Crop Group 2, etc.				
-- Potable Water				

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use	[Reserved] 3/			
-- Fish				
-- Irrigated Crops				
-- Field trials				
-- Processed Food/Feed				
-- Food Handling				
-- Meat/milk/poultry/eggs				

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ Data must be submitted no later than forty eight months from the issue date of the guidance package.
3/ The Agency is reserving all residue chemistry requirements until such time as those data necessary for an evaluation of Monuron-TCA's toxicology have been received and evaluated. Although the Agency does not have adequate data characterizing Monuron-TCA potential chronic effects, there are indications within the available literature that Monuron-TCA may pose some level of health risk. Should those data requested elsewhere within this standard indicate that Monuron-TCA does present a significant health risk, the Agency will make a determination as to whether or not petitions for tolerance will be necessary for the use in drainage ditches in Florida citrus groves.

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C	No	-	Yes
161-3 - On soil	TGAI or PAIRA	A	n/a [5]		
161-4 - In Air	TGAI or PAIRA	A,C	n/a		
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,C	No	-	[Reserved] [4]
162-2 - Anaerobic Soil	TGAI or PAIRA	A,C	n/a		
162-3 - Anaerobic Aquatic	TGAI or PAIRA	B	No	-	[Reserved] [4]
162-4 - Aerobic Aquatic	TGAI or PAIRA	B	No	-	[Reserved] [4]
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C	No		[Reserved] [4]
163-2 - Volatility (Lab)	TEP	A,C	n/a		
163-12- Volatility (Field)	TEP	A,C	n/a		

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,C	No	-	[Reserved] 4/
164-2 - Aquatic	TEP	B	No	-	[Reserved] 4/
164-3 - Forestry	TEP	A	n/a 5/		
164-4 - Combination and Tank Mixes			n/a		
164-5 - Soil, Long-term	TEP	A,C	n/a	-	
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	n/a		
165-2 - Rotational Crops (Field)	TEP	A	n/a		
165-3 - Irrigated Crops	TEP	B	No	-	[Reserved] 4/
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	[Reserved] 4/
165-5 - In Aquatic Non-Target Organisms	TEP	B	No	-	[Reserved] 4/

TABLE A
GENERIC DATA RTEQUIREMENTS FOR Monuron-TCA

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Non-Food; B=Aquatic, Non-Food; C=Domestic Outdoor.
3/ Data must be submitted no later than forty months from the issue date of the guidance package.
4/ The data for this chemical, Monuron-TCA, are being reserved, pending the evaluation of the corresponding data for monuron.
5/ N/a: Not applicable= Data requirement is not necessary for the purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,C	No	-	Yes
81-2 - Dermal LD_{50}	TGAI	A,B,C	No	-	Yes
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,C	n/a 6/		
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,C	n/a		
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	C	No	-	Yes 4/
82-2 - 21-Day Dermal	TGAI	A,B,C	No	-	[Reserved] 5/
82-3 - 90-Day Dermal	TGAI	A,B,C	n/a		
82-4 - 90-Day Inhalation - Rat	TGAI	A,B,C	n/a		
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI	A,B,C	n/a		

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,C	No	-	Yes 7/
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B,C	No	-	Yes 8/
83-3 - Teratogenicity - 2 species	TGAI	A,B	No	-	Yes
83-4 - Reproduction, 2-generation	TGAI	A,B,C	n/a 6/		
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B,C	No	-	Yes
84-2 - Chromosomal Aberration	TGAI	A,B,C	No	-	Yes
84-2 - Other Genotoxic Effects	TGAI	A,B,C	Partial	05009139	Yes 9/
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B,C	No	-	Yes
- Sulf and Methemoglobin	TGAI	A,B,C	No	-	Yes 10/

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

§158.135 Toxicology
(continued)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Non-Food; B=Aquatic, Non-Food; C=Domestic Outdoor.
3/ Data must be submitted no later than forty eight months from the issue date of the guidance package.
4/ These data will not be required should other data be submitted to the Agency which demonstrates the absence of detectable residues in crops receiving irrigation water from monuron treated ditches.
5/ This data requirement is reserved pending the receipt and evaluation of data relevant to Monuron-TCA dermal LD_{50}.
6/ N/a: Not applicable= Data requirement is not necessary for the purposes of this standard.
7/ Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies can be conducted.
8/ The Agency has become aware that the National Cancer Institute is concluding an oncogenicity study utilizing monuron. Until such time that this study may be received and evaluated, however, it may not be concluded that the study will satisfy Agency requirments. Registrants are, therefore, cautioned that they may remain liable for the satisfactory fulfillment of this data requirement.
9/ In vivo evaluations are required for the following tests: DNA damage and repair, numerical chromosomal aberrations, mammalian cell transformation, and target organ/cell analysis.
10/ Data relating the levels of sulf and methemoglobin following dietary exposure are being required by the Agency for all substituted phenylurea compounds. While this testing may be combined other required testing involving dietary exposure, dose levels must be such that a no observable effect level may be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,C	No	-	Yes 5/
71-2 - Avian Dietary LC_{50}	TGAI	A,B,C	No	-	Yes
71-3 - Wild Mammal Toxicity	TGAI	A,B,C	n/a 4/		
71-4 - Avian Reproduction	TGAI	A,B,C	n/a		
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,C	n/a		
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A,B,C	Partial	000030631	Yes 6/
	TEP	B	Partial	000034214	Yes 6/
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,C	No	-	Yes 7/
	TEP	B	No		Yes 7/
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A,B,C	No	-	Yes 8/
	TEP	B	No		Yes 8/

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
AQUATIC ORGANISM TESTING					
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B,C	n/a 4/		
72-5 - Fish - Life-Cycle	TGAI	A,B,C	n/a		
72-6 - Aquatic Organism Accumulation	TGAI,PAI Degradation Product	A,B,C	n/a		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B,C	n/a		
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A	Yes	00001999	No
141-2 - Honey bee toxicity of residues on foliage	TEP	A	n/a		
141-3 - Wild bees important in alfalfa pollination-toxicity of residues on foliage	TEP	A	n/a		
141-4 - Honey bee subacute feeding study	[Reserved] 9/				
141-5 - Field testing for pollinatorse study	TEP	A	n/a		

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
NONTARGET INSECT TESTING - AQATIC INSECTS:					
142-1 - Acute toxicity to aquatic inscts	[Reserved] 10/				
142-2 - Aquatic insect life-cycle study	[Reserved] 10/				
142-3 - Simulated or actual field testing for aquatic insects	[Reserved] 10/				
143-1- thru 143-3 NONTARGET INSECT TESTING PREDATORS AND PARASITES	[Reserved] 10/				

TABLE A
GENERIC DATA REQUIREMENTS FOR Monuron-TCA

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Non-Crop; B=Aquatic, Non-Food; C=Domestic Outdoor.
3/ Data must be submitted no later than forty eight months from the issue date of the guidance package.
4/ N/a: Not applicable= Data requirement is not necessary for purposes of this standard.
5/ Data are required for an avian acute oral LD_{50} on one species of upland gamebird (preferably Bobwhite quail).
6/ Walker, C.R. (1965) (MRID 5018708) may be reconsidered by the Agency for fulfillment of the data requirment for a 96-hour warmwater fish bioassay. In order for the Agency to make full use of the Walker study, satisfactory information regarding the dose related mortality and the percent active ingredient of both the technical and formulated products utilized in the study must be obtained and submitted for review. Should these data be either unavailable or unsuitable for Agency use, a 96-hour warmwater fish bioassay will remain as a data requirment.
7/ Data are required for a 48-hour freshwater invertebrate bioassay (preferably Daphnia magna).
8/ Data are required for a 48-hour marine invertebrate bioassay (preferably oyster larvae and shrimp).
9/ Reserved pending development of test methodology.
10/ Reserved pending decision as to whether data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Monuron-TCA

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	No	-	Yes 3/
61-2 - Statement of Composition	MP	No	-	Yes 3/
61-3 - Discussion of Formation of Ingredients	MP	No	-	Yes 3/
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	No	-	Yes 3/
62-2 - Certification of Limits	MP	No	-	Yes 3/
62-3 - Analytical Methods for Enforcement of Limits	MP	No	-	Yes 3/
Physical and Chemical Characteristics				
63-2 - Color	MP	No	-	Yes 4/
63-3 - Physical State	MP	Partial	005021075	Yes 4/
63-4 - Odor	MP	No	-	Yes 4/
63-7 - Density, bulk density, or specific gravity	MP	No	-	Yes 3/

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Monuron-TCA

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-12 - pH	MP	No	-	Yes[4]
63-14 - Oxidizing or reducing action	MP	No		Yes[4]
63-15 - Flammability	MP	No		Yes[5]
63-16 - Explodability	MP	No		Yes[4]
63-17 - Storage Stability	MP	No		Yes[4]
63-18 - Viscosity	MP	No		Yes[4]
63-19 - Miscibility	MP	Yes		No
Other Requirements				
64- 1 - Submittal of Samples	Choice	n/a[6]		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Monuron-TCA

§158.120 Product Chemistry
(continued)

1/ Composition: MP = Manufacturing-use product; Choice = of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than six months from the issue date of the guidance package.
3/ Certain of the required data are available to the Agency in previously submitted Confidential Statements of Formula. The Agency, however, has noted that in most cases these data are both incomplete and are in need of updating. The Agency, therefore, will require the submission of data for each manufacturing-use product undergoing registration or reregistration.
4/ Elements of the indicated data have been located by the Agency within standard references. The Agency cannot, however, apply this information to currently produced manufacturing use products due to possible variations in manufacturing processes. The indicated physical chemical properties data will, therefore, be required for each manufacturing use product undergoing registration or reregistration.
5/ Flammability data required for combustible liquids only.
6/ N/A: Not applicable= Data requirement is not considered necessary for purposes of this standard.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Monuron-TCA

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	No	-	Yes
81-2 - Dermal LD_{50}	MP	No	-	Yes
81-3 - Inhalation LC_{50}- Rat	MP	No	-	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes
81-5 - Primary Dermal Irritation	MP	No	-	Yes
81-6 - Dermal Sensitization	MP	No	-	Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING Monuron-TCA

§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than six months from the issue date of the guidance package.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

V. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 and V-2], as indicated by the following paragraphs of this section of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VI. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. William H. Miller
Product Manager 16
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-2600

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet". Refer to Appendix III-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report (Appendix IV-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Appendix III-2) with appropriate attachments.

C. You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

CASE BIBLIOGRAPHY

MRID

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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				

Appendix IV-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX V-2

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Manufacturing-Use Products and Certain End-Use Products Containing Monuron TCA as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this manufacturing-use standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the

steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Mr. Robert J. Taylor
Product Manager 25
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-1800

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: FIFRA Section 3(c)(2)(B) Notice for Manufacturing-Use Products and Certain End-Use Products Composed of Multiple Active Ingredients That Contain Monuron TCA As One of the Active Ingredients

Dear Registrant:

This is a notice to you that EPA is requiring registrants of pesticide products containing the subject active ingredient to arrange to submit data to EPA concerning that active ingredient. As this notice explains, within 90 days from your receipt of this letter you must inform EPA either (1) that you are exempt from this requirement, or (2) how you will comply with the requirement. If you do not respond, or if you otherwise fail to comply with this notice, EPA may suspend the registration of your products containing that active ingredient. Attachment A is a list of those products. The authority for this notice is Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. Section a(c)(2)(B).

I. Why You Are Receiving This Notice Now

EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978). Many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as were being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [see FIFRA Section 3(g)].

A new review procedure has been developed. Under it, EPA has issued Guidance Documents, each of which discussed a particular pesticide active ingredient. Each Guidance Document summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency currently does not have, compliance with standards of toxicity, composition, labeling, and packaging; and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D). Registrants of manufacturing-use products and certain end-use products have already received or will receive a copy of this enclosed Guidance Document.

FIFRA requires that a data submission requirement under Section 3(c)(2)(B) must be imposed on the registrants of all products to which the data are pertinent. Some of the data we have required persons subject to the reregistration program to submit are "generic" data which pertain to the safety of the active ingredient of a product, and thus are relevant to all products containing that ingredient (or to all products which contain that ingredient and have certain use patterns or formulation characteristics).

Since these data also may be pertinent to the registrability of your product containing the subject chemical, we are required by Section 3(c)(2)(B) to send you this notice. You are required to comply with this notice, but you are not required at this time to take steps to reregister your product, e.g., relabel your product.

II. What You Must Do to Comply With This Notice

Within 90 days of your receipt of this Notice, you must furnish to EPA a completed copy of the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Attachment B) with appropriate attachments for each of your products. Agency records indicate that you do not qualify for the FIFRA Section 3(c)(2)(D) data exemptions, since the source of subject active ingredient is (1) not registered with EPA or/and (2) is not purchased from a firm other than your own. Since you are not exempt, you must determine what data you are required to submit [see paragraph (A) below] and how you will comply with the requirement [see paragraphs (B) through (D) below].

A. What Generic Data Must Be Submitted

You may ascertain which generic data you must submit by consulting the generic data table (Table A in the

Guidance Document). That table shows the generic data needed to evaluate the continued registrability of all products containing the subject chemical and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, in the Pesticide Registration Guidelines*/, or data collected under protocols approved and issued by the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may submit an application to have your registration amended by deleting those uses.

After determining whether you are required to submit data, and if so, which data, choose the appropriate option for each of your affected products.

B. Options Available for Complying With Requirements to Submit Data

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Attachment B) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and
   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must state which of the parties to the agreement will respond to this Notice in the manner specified by paragraph c.2. above. A list of registrants with products containing this active ingredient is included for your information (see Attachment C).

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*/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data." (EPA Form 8580-6, Attachment D)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed.

5. Change the source of your active ingredient to one that is (1) registered with EPA and (2) purchased from a firm that does not have ownership in common

6. Request voluntary cancellation of the registration(s) of your product(s) for which the data are needed.

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

C. Timeframes for Development and Submission of Required Data

The periods listed in Table A of the Guidance Document are the periods which the Agency will allow for development and submission of the data (measured from the date of receipt of this Notice).

D. Procedures for Requesting Changes In Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports from the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you must submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager named below. The extension request should state the reasons why you conclude that an extension is appropriate. You must strive to meet the deadline for submitting the required data while EPA considers your request.

If, after reviewing this Notice, you do not understand what you must do, or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way.

Mr. Robert J. Taylor
Product Manager 25
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-1800

Sincerely yours,

Douglas D. Campt, Director
Registration Division (TS-767)